REMARKS

Allowable Subject Matter

In the Final Rejection, the Examiner states that Claims 10-12 and 17 are objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants have now done so and respectfully request that Claims 10-12 and 17 be allowed.

Applicant will now address the Examiner's remaining rejection.

Claim Rejections - 35 USC §103

In the Office Action, the Examiner rejects Claims 2-9 and 13-16 under 35 USC §103(a) as being unpatentable over Sahota (US 2003/0181973 A1) in view of Haverkost et al. (US 2003/0139806 A1). This rejection is respectfully traversed.

More specifically, independent Claim 2 of the present application is directed to a balloon catheter having an expandable balloon located at the distal end portion of the catheter, with a pouch disposed on at least a portion of the balloon, wherein the pouch expands and contracts with the inflation and deflation of the balloon, and wherein an area between the pouch and the portion of the expandable balloon is adaptive to receiving an agent when the balloon is not expanded. The expandable balloon has an annular ridge at both the distal and proximal end of the balloon with the pouch located between the annular ridges. The claimed balloon catheter is for inserting into the vascular system of a human wherein there is blockage (usually from plaque) within a vessel. The uninflated balloon on the distal end of the catheter is positioned at the spot of the blockage. The balloon is then inflated which disrupts and flattens the plaque against the arterial wall, and stretches the arterial wall, resulting in enlargement of the intraluminal passageway and increased blood flow.

This breaks-up the plaque and clears the blockage in the vessel. At the same time as the balloon is inflating, the pouch on the balloon is stretching and expanding. The expansion of the balloon then forces the drug through the pouch and into the vessel at the point of the balloon expansion (i.e. the blockage in the vessel). Thereafter, the balloon with pouch is deflated and removed from the body. One purpose of the claimed catheter is to break-up the blockage without having to leave a structure within the vessel in the body.

In order to make this feature clear, Applicant is amending Claim 2 to recite "wherein said pouch expands and contracts with said balloon and wherein said balloon and pouch are removable together from a patient."

In contrast, Sahota is directed to a stent and a stent delivery system for delivering at least two drugs to a treatment site. See [0019] in Sahota. Preferably, one drug is a quick release agent while the other drug is a slow release agent. See [0020]-[0021]. A stent is intended to be permanently left within the vessel, which is very different than the balloon catheter device of the claimed invention.

In the Final Rejection, the Examiner contends that Sahota discloses a pouch 700 (fig. 7J) disposed between the annular ridges on the balloon. However, in contrast to the balloon catheter of independent Claim 2 of the present application, the film in Sahota is either attached to the stent or formed on the stent (see e.g. [0080] in Sahota). With the device of Sahota, the stent is permanently placed in the vessel with the attached film. The film then either dissolves and is absorbed by the body, releasing the drug at the treatment site (see e.g. [0081]) or is a biostable polymer which stays with the stent. Hence, the film (i.e. the alleged pouch) is left in the body with the stent, unlike the pouch of the balloon catheter of Claims 2 of the present application wherein the balloon and pouch are removable together from the body.

As the Examiner admits, Sahota does not disclose a pouch that contracts and expands with the balloon (as recited in independent Claim 2).

The Examiner cites Haverkost and contends that it teaches that stents can radially contract. The Examiner then argues that it would have been obvious to modify Sahota's pouch and include the radially contracting characteristic of Haverkost. Applicant respectfully disagrees.

As explained above, Sahota is directed to a stent that is to stay in the body. As stated in Sahota, a major difficulty with PTA is post-angioplasty closure of the vessel immediately after PTA and that a stent is a means for preventing this immediate disclosure. [0006], [0011]. A stent that radially contracted would be counter to this purpose of Sahota.

The alleged "pouch" in Sahota is a film which is attached to the stent and left in the body to either dissolve, be absorbed by the body and release the two or more drugs while dissolving, or to be permanently attached to the stent in order to release the two or more drugs. There is no disclosure or suggestion in Sahota of a pouch which is able to contract with the balloon and wherein the balloon and pouch are removable together from a patient. In fact, such a modification would make the device of Sahota unsatisfactory for its intended purpose.

For example, the Summary of the Invention in Sahota states that the invention is directed to a drug delivery stent that delivers at least two and even multiple drugs to a treatment site. [0019]. These drugs are preferably a quick release drug and a slow-release drug. [0020]-[0021]. As a result, the alleged "pouch" or film in Sahota is designed to remain with the stent for release of the two drugs over time. If the Sahota device was modified to incorporate the feature of the claimed invention of a pouch which is able to expand and contract with the balloon and wherein the balloon and pouch are removable together from a patient, the device would no longer be suitable for its intended purpose, i.e. the release of two or more drugs, one being a quick release and one being a slow release drug.

As stated in MPEP 2143.01, "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)." Hence, this modification of Sahota to allegedly arrive at claimed invention is improper.

Therefore, the rejection of Claim 2 is improper, and the cited references do not disclose or suggest the balloon catheter of independent Claim 2 and those claims dependent thereon.

For similar reasons, the rejection of Claim 3 is improper, and the cited references do not disclose or suggest the balloon catheter of independent Claim 3 and those claims dependent thereon.

Accordingly, these claims are patentable thereover, and it is respectfully requested that this rejection be withdrawn.

CONCLUSION

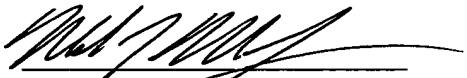
Therefore, for at least the above-stated reasons, the present application is in an allowable condition and should be allowed.

As this amendment is merely placing the application in a condition for allowance, it is respectfully requested that the amendment be entered.

Please charge our deposit account 50/1039 for any fee due for this amendment.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,



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